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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,911

08/18/2005

Ib Joergensen

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57360

7590

05/24/2010

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,911	Applicant(s) JOERGENSEN ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,13,21-31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,13,21-31 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action following the third Request for Continued Examination based on the 10/511911 application filed August 18, 2005. Claims 1, 4-8, 13, 21-31, and 33 as amended in the response filed March 8, 2010 are currently pending and considered below.

Claim Objections

1. Claim 1 recites the limitation "the proximal and distal portions" in line 10 of the claim and "the proximal and distal portions of the pipe" in line 14 of the claim. There is insufficient antecedent basis for these limitations in the claim. The examiner notes that the proximal and distal portions of line 10 are not given reference as to whether they are a portion of the catheter shaft or the guiding wire lumen pipe, however, based on the recitation at line 14 of the proximal and distal portions of the pipe, the examiner has interpreted the proximal and distal portions at line 10 to also be the proximal and distal portions of the pipe.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "the inflation lumen being formed between an exterior surface of the pipe and an interior surface of the catheter shaft", and the claim also recites "wherein the inflation lumen is defined by an annulus between an exterior of the pipe and an interior surface of the catheter shaft: which is the narrower statement of the range/limitation. For purposes of examination, the examiner will be treating that claim as if only the broader limitation were present.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 4-8, 13, 21-27, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 4,960,410 to Pinchuk in view of USPGPub 2002/0072730 A1 to McGill et al and in further view of USPGPub 2004/0102719 A1 to Keith et al.

Regarding the above claims, Pinchuk discloses a balloon catheter comprising a catheter shaft having a distal end (24), an inflatable balloon disposed on the distal end

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(12), a proximal end coupled to a connecting piece (30), a guiding wire lumen (22), and an inflation lumen formed between an exterior surface of the pipe and an interior surface of the catheter shaft (52). Pinchuk further discloses that the guiding wire lumen has coupled proximal (60) and distal (64) portions wherein the proximal portion is made of a more rigid metallic material and the distal portion is made of a less rigid plastic material (Col. 3, line 65-Col. 4, line 11).

Pinchuk fails to explicitly teach or disclose that a transitional portion is provided with kink protection at least partially overlapping the proximal and distal portions. However, McGill et al teach a kink protection portion (205) which extends over both a proximal and distal portion and is connected to the proximal and distal portions of the pipe (connected has been given its broadest reasonable interpretation to mean joined or linked together, Merriam Webster Online Dictionary; as such permanent fixation is not required). They further teach a second form a kink protection in the form of a metal coil (634), which the examiner believes could be placed inside or outside of the pipe. Furthermore, McGill et al teach a configuration wherein proximal and distal pipes meet end to end at a transition, wherein a kink protection is provided about the transition at least partially overlapping the proximal and distal pipes (Figs. 16 and 17).

Pinchuk and McGill et al fail to teach that the proximal portion of the pipe includes a friction reducing plastic tube within the lumen of the proximal portion. However, Keith et al teach using a polymer tube, such as PTFE (136) as a lubricious inner liner for a guide wire lumen (Paragraph [0061]) having a lubricity-enhancing coating (the surface of the tube adjacent the lumen).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Pinchuk with the kink protection sleeve or metal coil of McGill et al, as well as the transition configuration, in order to provide increased stability in the catheter when navigating tortuous regions, as well as provide a more predictable change in stiffness of the catheter between the proximal region and the distal region, while maintaining an appropriate level of kink protection. It would have also been obvious to further modify the catheter of Pinchuk and McGill et al with the lubricious liner of Keith et al to ensure ease of movement for a guide wire within the guide wire lumen [0061].

9. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, McGill et al, and Keith et al as applied to claim 27 above, and further in view of USPGPub 2003/0050600 A1 to Ressemann et al.

Ressemann et al further teach the limitation of plasma treating for increasing adherence, which the examiner asserts would be possible to do on either the interior of the catheter or the exterior of the plastic tubing of Keith et al. The examiner further asserts that this process renders the plastic tubing adherent, thereby making the outer layer adhesive. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the coating techniques of Ressemann et al with the catheter as stated above in order to ensure good adhesion of the friction-reducing interior polymeric layer.

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10. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, McGill et al, and Keith et al as applied to claim 1 above, and further in view of USPN 6,596,217 B1 to Davis-Lemessy et al.

Davis-Lemessy et al teach the use of a nylon tube in the construction of a catheter (Col. 4, lines 15-40), which is not taught by the combination of Claim 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the nylon tube construction of Davis-Lemessy et al in place of the plastic tubing of Keith et al in order to be able to fusion bond with nylon balloons (Col. 4, lines 15-40).

Response to Arguments

11. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763